## Food and Drug Administration, HHS

(b) Optional adjuvant substances. The basic resins identified in paragraph (a) may contain optional adjuvant substances used in their production. These adjuvants may include substances described in §174.5(d) of this chapter and the following:

Substance	Limitations
Diphenyl sulfone	Not to exceed 0.2 percent by weight as a residual solvent in the finished basic resin.

(c) Extractive limitations. The finished food contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields in each extracting solvent net chloroform soluble extractives not to exceed 0.05 milligrams per square inch of food contact surface: Distilled water, 50 percent (by volume) ethanol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane. In testing the final food contact article, a separate test sample shall be used for each extracting solvent.

[63 FR 20315, Apr. 24, 1998]

#### § 177.2420 Polyester resins, crosslinked.

Cross-linked polyester resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) The cross-linked polyester resins are produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols or epoxides listed in paragraph (a)(2) of this section, followed by copolymerization with one or more of the cross-linking agents listed in paragraph (a)(3) of this section:

(1) Acids:

Adipic.

Fatty acids, and dimers thereof, from natural sources.

Fumaric.
Isophthalic.
Maleic.
Methacrylic.
Orthophthalic.
Sebacic.
Terephthalic.
Trimellitic.

#### (2) Polyols and polyepoxides:

Butylene glycol. Diethylene glycol. 2,2-Dimethyl-1,3-propanediol. Dipropylene glycol. Ethylene glycol. Glycerol. 4,4'-Isopropylidenediphenol-epichlorohydrin. Mannitol. a-Methyl glucoside. Pentaerythritol. Polyoxypropylene ethers of 4,4'-isopropylidenediphenol (containing an average of 2-7.5 moles of propylene oxide). Propylene glycol. Sorbitol. Trimethylol ethane.

# 2,2,4-Trimethyl-1,3-pentanediol.(3) Cross-linking agents:

Butyl acrylate. Butyl methacrylate. Ethyl acrylate. Ethylhexyl acrylate. Methyl acrylate. Methyl methacrylate. Styrene.

Trimethylol propane.

Triglycidyl isocyanurate (CAS Reg. No. 2451-62-9), for use only in coatings contacting bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under type VIII.

Vinyl toluene.

(b) Optional adjuvant substances employed to facilitate the production of the resins or added thereto to impart desired technical or physical properties include the following, provided that the quantity used does not exceed that reasonably required to accomplish the intended physical or technical effect and does not exceed any limitations prescribed in this section:

List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
Inhibitors:     Benzoquinone  tert-Butyl catechol. TBHQ. Di-tert-butyl hydroquinone. Hydroquinone.	Total not to exceed 0.08 percent. 0.01 percent.
2. Accelerators:	Total not to exceed 1.5 percent.
Benzyl trimethyl ammonium chloride	0.05 percent.

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List of substances	Limitations (limits of addition expressed as percent by weight of finished resin)
Calcium naphthenate.	
Cobalt naphthenate.	
Copper naphthenate.	
N, N-Diethylaniline	0.4 percent.
N, N-Dimethylaniline	Do.
Ethylene guanidine hydrochloride	0.05 percent.
3. Catalysts:	Total not to exceed 1.5 percent, except that methyl ethyl ketone peroxide may be used as the sole catalyst at levels not to exceed 2 percent.
Azo-bis-isobutyronitrile.	'
Benzoyl peroxide.	
tert-Butyl perbenzoate.	
Chlorbenzoyl peroxide.	
Cumene hydroperoxide.	
Dibutyltin oxide (CAS Reg. No. 818–08–6)	For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin.
Dicumyl peroxide.	
Hydroxybutyltin oxide (CAS Reg. No. 2273-43-0)	For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin.
Lauroyl peroxide.	
<i>p</i> -Menthane hydroperoxide.	
Methyl ethyl ketone peroxide.	
Monobutyltin tris(2-ethylhexoate) (CAS Reg. No. 23850–94–4).	For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin.
4. Solvents for inhibitors, accelerators, and catalysts:	
Butyl benzyl phthalate (containing not more than 1.0 per-	
cent by weight of dibenzyl phthalate).	
Dibutyl phthalate. Diethylene glycol	As a solvent few honeyd trimothyd ammenium oblevide ay othyd
Dietriylerie giycoi	As a solvent for benzyl trimethyl ammonium chloride or ethylene quanidine hydrochloride only.
Dimethyl phthalate.	ene guanidine nydrochionde only.
Methyl alcohol.	
Styrene.	
Triphenyl phosphate.	
5. Reinforcements:	
Ashestos.	
Glass fiber.	
Polyester fiber produced by the condensation of one or	
more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols listed in paragraph	
(a)(2) of this section.	
Miscellaneous materials:	
Castor oil, hydrogenated.	
$\alpha$ -Methylstyrene.	
Polyethylene glycol 6000.	
Silicon dioxide.	0 1: 31 0 170 0740 (11: 1 )
Wax, petroleum	Complying with § 178.3710 of this chapter.

- (c) The cross-linked polyester resins, with or without the optional substances described in paragraph (b) of this section, and in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of their intended use, as determined from tables 1 and 2 of §176.170(c) of this chapter, shall meet the following extractives limitations:
- (1) Net chloroform-soluble extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simu-

lating solvent is water or 8 or 50 percent alcohol.

- (2) Total nonvolatile extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is heptane.
- (d) In accordance with good manufacturing practice, finished articles containing the cross-linked polyester resins shall be thoroughly cleansed prior to their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 37618, Aug. 19, 1983; 54 FR 48858, Nov. 28, 1989]